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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/823,038	03/28/2001	Lorna Strachan	11000.1037c3	1046

7590 05/17/2002

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EXAMINER

LI, RUIXIANG

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 05/17/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/823,038

Applicant(s)

STRACHAN

Examiner

Ruixiang Li

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 April 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-21 and 23-28 is/are pending in the application.
- 4a) Of the above claim(s) 13-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 March 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4</u> | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Election/Restrictions

1. Applicants' election the invention of claim 22, drawn to a method for enhancing an immune response in a patient, as directed to SEQ ID NO: 33, in Paper No. 10 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Applicants' amendment in Paper No. 10 has been entered in full. Claims 1-12 and 22 have been canceled. New claims 23-28 have been added. Claims 13-21 and 23-28 are pending. Claims 23-28 as directed to SEQ ID NO: 33 are under consideration and all other claims are withdrawn from consideration.

Objection to the Disclosure

3. The disclosure is objected to because (1) there is an error in reference to related patent application. The issued U. S. Patent No. is 6,242,419, not 6,424,419. Applicant is required to correct the error; (2) the disclosure contains an embedded hyperlink (e.g., page 9, line 13; page 11, lines 13, 21, and 25; page 22, line 14). Applicant is required to delete the embedded hyperlink. See MPEP § 608.01

Drawings

4. The drawings, Figs. 1-9, have been accepted by the examiner.

Information Disclosure Statement

5. The information disclosure statement filed July 12, 2001 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. The information of *references on sequence data* from Databases is incomplete. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that *a new PTO-1449 form be submitted for the current application* and that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C(1).

Claim Rejections—35 USC § 112, 1st paragraph

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 25-28 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the methods wherein the polypeptide comprises SEQ ID NO: 33, does not reasonably provide enablement for the methods reciting a genus of polypeptides comprising sequences having at least 75% or 90% identity to SEQ ID NO: 33. The specification does not enable any person skilled in

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the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The factors that are considered when determining whether a disclosure satisfies enablement requirement include: (i) the quantity of experimentation necessary; (ii) the amount of direction or guidance presented; (iii) the existence of working examples; (iv) the nature of the invention; (v) the state of the prior art; (vi) the relative skill of those in the art; (vii) the predictability or unpredictability of the art; and (viii) the breadth of the claims. *Ex Parte Forman*, 230 USPQ 546 (Bd Pat. App. & Int. 1986); *In re Wands*, 858 F. 2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988).

Claims 25-28 are drawn to a method for modulating an immune response comprising administering a genus of polypeptides comprising sequences which are at least 75% or 90% identical to SEQ ID NO: 33. However, other than SEQ ID NOS: 33, the disclosure only discloses one polypeptide set forth in SEQ ID NO: 31, which shares 77.1% homology with SEQ ID NO: 33 (See attached sequence alignment). The disclosure does not provide sufficient guidance and information regarding the structural and functional requirements commensurate in scope with what is encompassed by the instant claims. The disclosure does not show (i) which portions of SEQ ID NO: 33 are critical to the activity of the protein; and (ii) what modifications (e.g., substitutions, deletions or additions) one can make to SEQ ID NO: 33 will result in protein mutants with the same functions as the claimed protein. The state of the art (See, e.g., Ngo, et al, *The Protein Folding Problem and Tertiary Structure Prediction*, 1994, Merz, et al. (ed.), Birkhauser, Boston, MA, pp. 433 and 492-495) is such that the relationship between sequence of a protein and its activity is not well understood

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and is not predictable. Excising out portions of a protein or modifications to a protein, e.g., by substitutions or deletions, would often result in deleterious effects to the overall activity and effectiveness of the protein.

In addition, the claims, as written encompass any sequences as long as they comprises at least 75% or 90% identity to SEQ ID NO: 33. Sequences obtained from sources other than human or prepared by chemical synthesis may act as immunogens and cause immune response in a patient.

Accordingly, the disclosure fails to enable such a myriad of the claimed polypeptides that not only vary substantially in length but also in amino acid composition and to provide any guidance to one skilled in the art on how to make and use the claimed genus of polypeptides. Thus, it would require undue experimentation for one skilled in the art to make and use the claimed genus of the molecules embraced by the instant claims.

Claim Rejections—35 USC § 112, 2nd paragraph

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 23-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 23-28 are indefinite because the steps recited in the method do not necessarily achieve the goal set forth in the claim preamble.

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In addition, the claim preamble is inconsistent with the effect of the method. Claims 23, 25, and 27 recite a method for modulating an immune response in a patient, whereas claims 24, 26, and 28 recite "the immune response is enhanced".

Claim Objections

10. Claims 23-28 are objected to because each claim recites unelected subject matter (SEQ ID NOS: 31 and 32). Appropriate correction is required.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (703) 306-0282. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this Group is (703) 305-3014 or (703) 308-4242.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

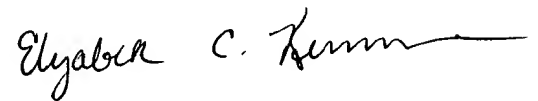
All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35

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U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Ruixiang Li
Examiner
May 13, 2002

A handwritten signature in cursive script, reading "Elizabeth C. Kemmerer", followed by a horizontal line.

ELIZABETH KEMMERER
PRIMARY EXAMINER